

Submitter:

MAY 11 2001

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January 24, 2001

1. Definition and Intended Use

CG-900P is an ambulatory Fetal/Maternal Monitor intended for monitoring fetal Heart Rate (FHR) and Maternal Uterine Activity (TOCO) and for marking of fetus movement. The correlation between these parameters provides a physician with important predictors of fetal well being.

- a. The Fetal/Maternal data is recorded and transmitted to a remote receiving station via data communication line for consultation with a physician.
- b. The data is recorded and transferred to a PC for viewing and processing.

The device incorporates a recording and transmitting circuitry, graphic LCD, a package of firmware.

The CG-900P may receive, store and retransmit the maternal Noninvasive Blood Pressure (NIBP) measured by an external device.

The Optical Encoder enables input of maternal data: weight, urine albumin and glucose.

The CG-900P utilizes clinically verified routinely used methods, which have been widely approved and accepted by the medical community.

- Doppler ultrasound technique for FHR measuring,
- Strain gauge transducer for relative pressure of uterine contraction (TOCO) measuring

The FHR and TOCO traces are displayed on screen in real time during a test. The traces and data are stored in memory and retrieved for display and transmission.

The CG-900P is compatible and intended for use with TM 2000, the Card Guard's standard Transtelephonic Receiving Center in its LAN as well as its standalone configuration.

The CG-900P is classified as Class II medical device.

The CG-900P meets the requirements of the following standards:

- (1) IEC-601-1-4 Medical Electrical Equipment 1996.

2. Features and Functions

- (1) Graphic LCD for signal and data representation and device control.
- (2) Optical Encoder for device control and data input.
- (3) On/Off button for device energizing.
- (4) Recorded data transmitted acoustically or via modem.
- (5) Low battery detection.



3. Substantial Equivalence

The CG-900P is a simplified and improved version of the Ambulatory Fetal/Maternal Monitor, model CG-900 (K960553). Therefore the CG-900P is equivalent to its predicate device: the CG-900.

4. Material differences

The most important innovations in CG-900P include:

- The new device version is radically miniaturized and elegantly designed features contemporary state-of-the-art ergonomic LCD, packaging and controls. Its mass without accessories is only 960 gr. comparing to CG-900 Monitor's 7.5 Kg.
- The vital signs: Maternal NIBP, Maternal SpO₂, which were monitored by the predicate device can now be input from the external source for transtelephonic transmission.

5. Design Controls and Hazard Analysis

The Card Guard's product design procedure, and QA and QC policy, formalize the design and production process and assure that all respective requirements are met. In the framework of the Design Controls the laboratory testing was conducted to verify and validate the CG-900P compliance with all the design specifications. This included:

Verification Tests	Validation tests
<i>SW Unit/Module Testing</i>	<ul style="list-style-type: none"> • FHR Measuring Accuracy Test • TOCO Measuring Accuracy Test
<ul style="list-style-type: none"> • FHR Sample • Graphic Display Manager • Low Battery Module • Optical Encoder Manager • Real Time Display • Recording • Serial Communication Manager • System Initialization Module • Text Display Manager • Transmit IR 	<p>Safety tests</p> <ul style="list-style-type: none"> • Safe Current Test
<i>Hardware Test Reports</i>	<p>Environmental Tests</p> <ul style="list-style-type: none"> • High and Low Temperature and Humidity Test • Surface temperature Test • Leakage Current Test • Dielectric Strength Test • Mechanical Vibration Shock Test • Ingress of Liquids Test • EMC Test
<i>User Interface Test Report</i>	

The device biocompatibility was evaluated and found to be satisfactory.

The device Level of Concern criteria were evaluated and CG-900P was characterized as a moderate level of concern system.

The System Safety and Risk analysis conducted for CG-900P provided rigorous design and structural evaluation aimed at revealing potential failures or possible system flaws which could directly or indirectly effect the patient.

6. Conclusions

The CG-900P constitutes a safe and reliable means for recording and transmitting the Fetal/Maternal data for the purpose of cardiac condition diagnosis. Its material composition and operation present no adverse health effect or safety risks to patients when used as intended.

The conclusions drawn from clinical and laboratory testing of the CG-900P demonstrate that the device is as safe, as effective and performs as well as or better than the legally marketed predicate device.



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Food and Drug Administration
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Mr. Alex Gonorovsky
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Regulatory Affairs
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ISRAEL

Re: K010552
CG-900P Fetal/Maternal Monitor
Dated: April 10, 2001
Received: April 13, 2001
Regulatory Class: II
21CFR §884.2740/Procode: 85 HGM

Dear Mr. Gonorovsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)



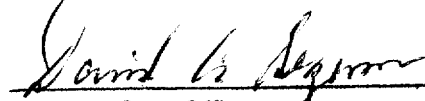
Indications For Use
CG-900P Fetal/Maternal Monitor

510(k) Number: k010552

- (1) The CG-900P is an ambulatory (non-stationary) Fetal/Maternal Monitor intended for use as follows:
- home care: administrated by a healthcare practitioner
 - clinics and hospitals, under physician supervision
- (2) The CG-900P is intended for both antepartum and intrapartum monitoring

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010552

Prescription Use ☒ or Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)